



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Food and Drug Administration  
Washington DC 20204

DEC 9 1997

Richard S. Silverman and  
Martin J. Hahn  
Hogan & Hartson L.L.P.  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004-1109

Dear Messrs. Hahn and Silverman:

This letter is a follow-up to our meeting on September 25, 1997, at which we discussed the use of "tasteless smoke" to treat cuts of fresh tuna prior to freezing for transport to the U.S. Our discussion essentially followed the issues presented in your letter to this office, dated September 19, 1997, asserting that the smoking process and product labeling described in your letter do not violate certain provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

You requested the meeting on behalf of your client, Hawaii International Seafood, Inc., in response to an opinion stated in a letter of August 14, 1997, from the Office of Seafood concerning the regulatory status of products that have been subjected to processes that use carbon monoxide (CO) or tasteless smoke to enhance the red color of tuna flesh. The August 14, letter addressed two issues: (1) the status of CO as a food additive; and (2) the economic adulteration of tuna with CO or an agent containing CO.

In our August 14, letter we stated that we believe that CO results in the adulteration of any food to which it has been added because CO is not approved for use in or on food. We also stated that the use of CO to deceptively alter the color of tuna would also cause the product to be economically adulterated, as would any such agent (including tasteless smoke) if used to deceptively alter the color. Specifically, we stated:

Therefore, without regard to other violations under ~~sections 402(a)(2)(C) or 402(c) of the Act, the use of CO~~ results in economic adulteration under section 402(b)(4) of the Act because it makes the tuna "appear better or of

Exhibit D

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greater value than it is." The fact that the addition of CO to food may result from treatment with some form of smoke or other ingredient, labeled or unlabeled, is a separate matter, it does not alter a charge of economic adulteration under section 402(b)(4).

While supporting our position with regard to the use of CO to process raw tuna, in your letter you "disagree with the agency position that tasteless smoke should be subject to the same restrictions as CO." You state that "tasteless smoke is a generally recognized as safe (GRAS) ingredient" and therefore is not required to undergo premarket approval. We have advised you to pursue the food additive status of tasteless smoke for the described use on raw tuna flesh with the Center for Food Safety and Applied Nutrition, Office of Premarket Approval.

According to your letter, tasteless smoke is traditional wood smoke that has been filtered through ice and activated charcoal to remove "phenols, particulate matter and other taste components," and as applied by Hawaii International Seafood, Inc., the treatment with "tasteless smoke functions as a preservative in the raw tuna" and "it fixes rather than imparts color." However, as you indicate, the modified smoke still contains CO and other components that may interact with tuna myoglobin to impart color.

As explained at our meeting, the August 14, letter responded to the specific issue of using CO or other agents, including smoke, to change the color of the tuna flesh in a way that might mislead consumers about the true nature or value of the treated product. If the process that you have described extends the shelf-life of the thawed tuna without imparting any misleading effects, then we agree that treated tuna would not necessarily be economically adulterated under section 402(b)(4) of the act simply because the smoke contained CO. It was not our intent to imply otherwise.

In making this clarification, we have set aside any consideration of other food additive or labeling issues that may be associated with the use of tasteless smoke on raw tuna. The Food and Drug Administration has not had the opportunity to examine tuna that has been processed as described, or to review information and data bearing on the specific conditions and controls used in the production of these products.

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We understand that Hawaii International Seafood, Inc., plans to notify the agency's Office of Premarket Approval that they have made a determination that tasteless smoke is a GRAS food

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ingredient, and to present supporting data that is presently being collected, including any affects on the color and preservation of the tuna flesh.

We look forward to reviewing this data and hope that this letter responds to your concerns for any unintended characterization that may have been inferred about products treated with tasteless smoke in our letter of August 14, 1997.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'P. Spiller', with a large, sweeping flourish extending to the left.

Philip C. Spiller  
Director  
Office of Seafood  
Center for Food Safety  
and Applied Nutrition